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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/726,258	11/29/2000	Vanessa Hsei	P1085R4-1AC1	4895

7590 08/27/2004  
Knobbe Martens Olson & Bear LLP  
Ginger R Dreger  
Sixteenth Floor  
620 Newport Center Drive  
Newport Beach, CA 92660

EXAMINER

HELMS, LARRY RONALD

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 08/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/726,258

Applicant(s)

HSEI ET AL.

Examiner

Larry R. Helms

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 June 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 25,29 and 31-43 is/are pending in the application.
- 4a) Of the above claim(s) 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25,29,31-36 and 38-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Claims 1-24, 26-28, 30 are canceled.  
  
Claims 25, 29, 31, 33, 34, 36, 37, 38, 39 have been amended.  
  
Claim 43 has been added.
2. Claims 37 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species.
3. Claims 25, 29, 31-36, 38-43 are under consideration in the instant application.
4. Applicant's traversal of the withdrawal of claim 37, in the Remarks filed 6/15/04 is acknowledged. Applicant's traversal is on the grounds that claim 37 is within the elected subject matter and should be considered. While rejoinder of the claims reciting at least 40 kD would be appropriate upon allowance of claims reciting "at least 20 kD", at present these claims stand rejected and rejoinder is therefore not appropriate.
5. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action
6. The following Office Action contains NEW GROUNDS of rejection necessitated by amendment.

### ***Rejections Withdrawn***

7. The rejection of claims 29, 33-34, 38 and 41-42 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendments to the claims.

8. The rejection of claims 29, 38 and 41-42 under 35 U.S.C. 112, first paragraph is withdrawn in view of the amendments to the claims.
9. The rejection of claims 1, 25, 31-32 and 34-35 under 35 U.S.C. 102(b) as being anticipated by Griffiths et al. (WO 96/09325) is withdrawn in view of the amendments to the claims.
10. The rejection of claims 1, 25, 31-33 and 36 under 35 U.S.C. § 103(a) as being unpatentable over Zapata et al. (FASEB J. 1995, Abstract #1288, 9:A1479, IDS # 98) in view of Braxton (US Pat. No. 5,766,897, IDS #20) is withdrawn in view of the amendments to the claims.
11. The rejection of claims 26 and 28 under 35 U.S.C. § 103(a) as being unpatentable over Zapata et al. (FASEB J. 1995, Abstract #1288, 9:A1479, IDS # 98) in view of Braxton (US Pat. No. 5,766,897, IDS #20) as applied to claims 1, 25, 31-33 and 36 above, and further in view of Doerschuk et al (U.S. Patent No. 5,702,946, IDS #18) is withdrawn in view of the amendments to the claims.
12. The rejection of claims 34 and 35 under 35 U.S.C. § 103(a) as being unpatentable over Zapata et al. (FASEB J. 1995, Abstract #1288, 9:A1479, IDS # 98) in view of Braxton (US Pat. No. 5,766,897, IDS #20) as applied to claims 1, 25, 31-33 and 36 above, and further in view of Griffiths et al (U.S. Patent No. 5,670,132, IDS #13) is withdrawn in view of the amendments to the claims.

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***The following are NEW GROUNDS of rejections***

***Double Patenting***

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 25, 29, 31-36, 38-43 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5-6, 12, 15-17 of U.S. Patent No. 6133426 in view of Griffiths et al. (WO 96/09325).

The claims in the instant application are directed to conjugates of antibody fragments with a light chain of SEQ ID NO:56 or 62 conjugated to PEG of 20kD. The claims in the 6133426 patent are directed to antibodies with a light chain of SEQ ID NO:56 or 62. The patent does not teach attachment of PEG to the antibody. This deficiency is made up for in the teachings of Griffiths et al.

Griffiths et al. teach a conjugate comprising a radioantibody fragment and a PEG molecule (see entire document, e.g., Abstract). Griffiths et al. teach that the antibody can be an Fab' fragment (see, e.g., page 4 at lines 23-34). Griffiths et al. also teach

that the PEG used in the conjugate may be from 1,000 to 30,000 (i.e., 1 kD to 30 kD) in size (see page 5, especially lines 6-13). Griffiths et al. also teach that the PEG may be covalently attached to the thiol group in the hinge region of the molecule (e.g., page 5 at lines 14-19). Radiolabeling of antibodies, including Fab' fragments, is also taught (e.g., pages 8-9). Formulation in a sterile carrier is taught at page 12.

Although Griffiths et al. is silent regarding the apparent and relative sizes of these conjugates, Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be envisioned properties of an Fab' covalently attached to a PEG of 20 kD.

Thus it would have been obvious to label the antibody of patent 6133426 with a PEG as described by Griffiths et al for enhancing the clearance rate and reducing renal uptake.

Claims 25, 29, 31-36, 38-43 directed to an invention not patentably distinct from claims 1-3, 5-6, 12, 15-17 of commonly assigned 6133426. Specifically, see above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned 6133426, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 35 U.S.C. 103(c) and 37 CFR 1.78(c) to either show that the conflicting inventions were commonly owned at the

time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

15. Claims 25, 29, 31-36, 38-43 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 8-9, 11, 18 of U.S. Patent No. 6117980 in view of Griffiths et al. (WO 96/09325).

The claims in the instant application are directed to conjugates of antibody fragments with a light chain of SEQ ID NO:56 or 62 conjugated to PEG of 20kD. The claims in the 6117980 patent are directed to antibodies with a light chain of SEQ ID NO:56. The patent does not teach attachment of PEG to the antibody. This deficiency is made up for in the teachings of Griffiths et al.

Griffiths et al. teach a conjugate comprising a radioantibody fragment and a PEG molecule (see entire document, e.g., Abstract). Griffiths et al. teach that the antibody can be an Fab' fragment (see, e.g., page 4 at lines 23-34). Griffiths et al. also teach that the PEG used in the conjugate may be from 1,000 to 30,000 (i.e., 1 kD to 30 kD) in size (see page 5, especially lines 6-13). Griffiths et al. also teach that the PEG may be covalently attached to the thiol group in the hinge region of the molecule (e.g., page 5 at

lines 14-19). Radiolabeling of antibodies, including Fab' fragments, is also taught (e.g., pages 8-9). Formulation in a sterile carrier is taught at page 12.

Although Griffiths et al. is silent regarding the apparent and relative sizes of these conjugates, Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be envisioned properties of an Fab' covalently attached to a PEG of 20 kD.

Thus it would have been obvious to label the antibody of patent 6117980 with a PEG as described by Griffiths et al for enhancing the clearance rate and reducing renal uptake.

Claims 25, 29, 31-36, 38-43 directed to an invention not patentably distinct from claims 1-3, 8-9, 11, 18 of commonly assigned 6117980. Specifically, see above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned 6117980, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 35 U.S.C. 103(c) and 37 CFR 1.78(c) to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.


**Conclusion**

16. No claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (571) 272-0832. The examiner can normally be reached on Monday through Friday from 6:30 am to 4:00 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffery Siew, can be reached at (571) 272-0787.

18. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center telephone number is 703-872-9306.

Larry R. Helms  
571-272-0832

  
LARRY R. HELMS, PH.D  
PRIMARY EXAMINER